

510(k) Summary

MAR 6 2002

K020369

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3831

Contact Person: Sherri L Coenen

Date Prepared: February 1, 2002

Device Name Proprietary name: Elecsys® Anti-Tg CalCheck

Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed + unassayed)

Predicate device The Elecsys® Anti-Tg CalCheck is substantially equivalent to the currently marketed Elecsys® TSH CalCheck (K963147).

Device Description The Elecsys® Anti-Tg CalCheck is a lyophilized product manufactured using a human serum base, human Anti-Tg, and preservative. The analyte is appropriately spiked into the CalCheck matrix to the correct concentration levels.

510(k) Summary, Continued

Intended use	The Elecsys® Anti-Tg CalCheck is used in the verification of the calibration established by the Elecsys® Anti-Tg reagent on Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.
Comparison to predicate device	The Elecsys® Anti-Tg CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® TSH CalCheck (K963147).
Performance Characteristics	The Elecsys® Anti-Tg CalCheck was evaluated for value assignment and stability.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sherri L. Coenen
Regulatory Affairs, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

MAR 6 2002

Re: k020369
Trade/Device Name: Elecsys® Abti-Tg CalCheck
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: February 1, 2002
Received: February 4, 2002

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K020369

Device Name: Elecsys® Anti-Tg CalCheck

Indications For Use:

Elecsys® Anti-Tg CalCheck calibration verification solutions comprise three levels - low, mid, and high - each with a defined Anti-Tg concentration. The low solution concentration is near the lower detection limit of the assay. The middle solution is in the middle or at a clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys® Anti-Tg CalCheck is intended for use in the verification of the calibration established by the Elecsys® Anti-Tg reagent on Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

Susan S. Altare

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K020369